IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

JULIE TUTTLE, individually and on behalf of the ESTATE OF MICHAEL PAUL TUTTLE,	:	**CASE NO. 1:20-cv-04744**
Plaintiff,	:	**JUDGE LEIGH MARTIN MAY**
v.	:	
DEXCOM, INC.,	:	
Defendant.	:	

DEFENDANT DEXCOM, INC.'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendant Dexcom, Inc. files this Answer and Defenses to plaintiff's First Amended Complaint.

ALLEGED JURISDICTION AND VENUE[1]

1. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the First Amended Complaint, and therefore denies those allegations.

2. Dexcom admits that it is organized under Delaware law and that it maintains its principal place of business in California. The remaining allegations in paragraph 2 of the First Amended Complaint are legal conclusions to which no

[1] The headings and sub-headings from the First Amended Complaint are restated in this Answer for consistency and clarity purposes. To the extent those headings contain allegations that require a response, Dexcom expressly denies each and every such allegation.

response is required. To the extent a response is required, Dexcom denies all other allegations in paragraph 2 of the First Amended Complaint.

3. Dexcom admits that plaintiff originally filed her Complaint in the Superior Court of Gwinnett County, Georgia. The remaining allegations in paragraph 3 of the First Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Dexcom denies all other allegations in paragraph 3 of the First Amended Complaint.

4. Dexcom admits only that plaintiff attempted to serve it with an original Complaint on October 27, 2020. Dexcom denies all remaining allegations in paragraph 4 of the First Amended Complaint.

5. Dexcom admits that on November 20, 2020, Dexcom timely filed a Notice of Removal of plaintiff's original Complaint to this Court. Dexcom further admits that plaintiff did not seek remand of the Complaint to the Superior Court of Gwinnett County, Georgia.

6. The allegations in paragraph 6 of the First Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Dexcom admits that venue and jurisdiction are proper in the Northern District of Georgia.

THE ALLEGED G6 SYSTEM

7. Dexcom admits that it designs, manufactures, and sells the Dexcom G6. Dexcom admits that it provides a User Guide, as incorporated into plaintiff's complaint and attached to the First Amended Complaint as Exhibit A, that provides instructions and warnings related to use of the Dexcom G6. Answering further, those instructions and warnings were reviewed and required by the FDA as part of its clearance of the Dexcom G6 through the 510(k) De Novo process.

8. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 8 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the indications for use of the Dexcom G6. Dexcom admits only that one of the indications for use of the Dexcom G6 is to replace fingerstick blood glucose testing for diabetes treatment decisions. Dexcom denies all other allegations in paragraph 8 of the First Amended Complaint.

9. Dexcom denies that plaintiff completely or accurately characterizes or quotes from the website referenced in paragraph 9 of the First Amended Complaint.

10. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 10 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the indications for use of the Dexcom G6. Dexcom admits only that one of the indications for use of the Dexcom G6 is to aid in the detection of hyperglycemia and hypoglycemia

facilitating long-term therapy adjustments. Dexcom denies all other allegations in paragraph 10 of the First Amended Complaint.

11. Dexcom admits that it provided a User Guide with the Dexcom G6 that was prescribed to decedent. Dexcom further admits that FDA set requirements for the Dexcom G6 labeling and also issued special controls regarding the warnings to a user of the possibility of sensor signal drop-out or loss of communication with a digitally connected device, and that Dexcom provided such a warning in compliance with FDA requirements. (*See* FDA Decision Summary, attached as Ex. 1.)

12. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 12 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the components of the Dexcom G6. Dexcom admits that the Dexcom G6 consists of three main components: a sensor, a transmitter, and a display device. Dexcom denies any other allegations in Paragraph 12 of the First Amended Complaint.

13. Dexcom admits that it designs, manufactures, and sells the Dexcom G6 sensor, and that the sensor is part of the G6 System which is accompanied by a User Guide that provides instructions and warnings related to use of the Dexcom G6 that were reviewed and required by the FDA as part of its clearance of the Dexcom G6 through the De Novo process. Dexcom denies all other allegations in paragraph 13 of the First Amended Complaint.

14. Dexcom admits that it designs, manufactures, and sells the Dexcom G6 transmitter and that the transmitter is part of the G6 System which is accompanied by a User Guide that provides instructions and warnings related to use of the Dexcom G6 that were reviewed and required by the FDA as part of its clearance of the Dexcom G6 through the De Novo process. Dexcom denies all other allegations in paragraph 14 of the First Amended Complaint.

15. Dexcom denies that plaintiff completely or accurately characterizes the Dexcom G6 application for iPhones or the website referenced in paragraph 15 of the First Amended Complaint. Dexcom further denies that it manufactured the Dexcom G6 System Mobile App. Dexcom admits that it designs and develops mobile apps for its devices and that the User Guide provides instructions and warnings related to use of those mobile applications, and that a user may use the Dexcom G6 System Mobile App to view data on compatible personal mobile devices as a display device. Dexcom denies all other allegations in paragraph 15 of the First Amended Complaint.

16. Dexcom denies the allegations in paragraph 16 of the First Amended Complaint as stated. Dexcom admits that failure of a diabetic to be aware of their glucose levels can result in injury or death.

17. Dexcom denies the allegations in paragraph 17 of the First Amended Complaint as stated. Dexcom admits that failure of a diabetic to recognize hyperglycemia or hypoglycemia can result in injury or death.

18. Dexcom admits that the Dexcom G6 is available only by prescription.

19. Dexcom denies that plaintiff has fully and completely quoted from or characterized the MAUDE database in paragraph 19 of the First Amended Complaint. Dexcom denies the remaining allegations in paragraph 19 of the First Amended Complaint. Answering further, Dexcom responds that "a causal relationship cannot be established between production and reactions listed in a [MAUDE] report." Device Adverse Event Overview, available at https://open.fda.gov/apis/device/event/ (last visited Jan. 22, 2021.)

20. Plaintiff has not fully and completely quoted from the MAUDE database referenced in paragraph 20 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the relevant MAUDE data. Dexcom denies the allegations in paragraph 20 of the First Amended Complaint. Answering further, Dexcom responds that "a causal relationship cannot be established between production and reactions listed in a [MAUDE] report." Device Adverse Event Overview, available at https://open.fda.gov/apis/device/event/ (last visited Jan. 22, 2021.)

21. Plaintiff has not fully and completely quoted from the MAUDE database referenced in paragraph 21 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the relevant MAUDE data. Answering further, Dexcom responds that "a causal relationship cannot be established between production and reactions listed in a [MAUDE] report." Device Adverse Event Overview, available at https://open.fda.gov/apis/device/event/ (last visited Jan. 22, 2021.)

22. Plaintiff has not fully and completely quoted from the MAUDE database referenced in paragraph 21 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the relevant MAUDE data. Answering further, Dexcom responds that "a causal relationship cannot be established between production and reactions listed in a [MAUDE] report." Device Adverse Event Overview, available at https://open.fda.gov/apis/device/event/ (last visited Jan. 22, 2021.)

ALLEGED FDA CLASSIFICATION AND REVIEW OF MEDICAL DEVICES

23. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 23 of the First Amended Complaint, and no response to the allegations in paragraph 23 of the First Amended

Complaint is required.[2] To the extent a response is required, Dexcom admits that FDA has established a classification system for medical devices, but denies that plaintiff has accurately referenced or described the relevant FDA review process in this case in paragraph 23 of the Complaint.

24. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website in paragraph 24 of the First Amended Complaint, and no response to the allegations in paragraph 24 of the First Amended Complaint is required because the allegations in paragraph 24 are legal conclusions to which no response is required. To the extent a response is required, Dexcom admits only that FDA classifies medical devices using a risk benefit analysis that considers safety and the potential risks posed. Answering further, Dexcom admits that FDA has established a classification system for medical devices, but denies that plaintiff has accurately referenced or described the relevant FDA classification or review process relevant to this case in paragraph 24 of the Complaint.

25. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 25 of the First Amended Complaint, and no response to the allegations in paragraph 25 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are

[2] Plaintiff cites to hyperlinks to FDA Guidance throughout the First Amended Complaint, but avers only excerpts of the Guidance. Guidance represents FDA's current thinking on a topic, and FDA notes that an alternative approach may be utilized if it satisfies the requirements of applicable statutes and regulations. *Guidances*, https://www.fda.gov/industry/fda-basics-industry/guidances (last visited Jan. 22, 2021).

otherwise legal conclusions. To the extent a response is required, Dexcom admits that devices are classified as Class I, II, or III, depending on the potential risks posed, but denies that plaintiff has accurately referenced or described the relevant FDA review process in this case in paragraph 25 of the Complaint.

26. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 26 of the First Amended Complaint, and no response to the allegations in paragraph 26 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. To the extent a response is required, Dexcom admits that medical devices are subject to general controls but denies that plaintiff has accurately referenced or described the relevant FDA review process in this case in paragraph 26 of the Complaint.

27. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 27 of the First Amended Complaint, and no response to the allegations in paragraph 27 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. To the extent a response is required, Dexcom admits only that FDA review and marketing clearance is required to market medical devices, but denies that plaintiff has accurately referenced or described the relevant FDA review process in this case in paragraph 27 of the Complaint.

28. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 28 of the First Amended Complaint, and no response to the allegations in paragraph 28 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom further denies that plaintiff has accurately or completely characterized the premarket review process in paragraph 28 of the First Amended Complaint. Answering further, Dexcom states that Class II devices may be cleared by the FDA through the De Novo process for novel Class II medical devices, in which the FDA evaluates data to support the accuracy of a device, as well as the design, manufacturing, and labeling of a device for safety and effectiveness, and may clear the device with general and special device-specific controls. Dexcom further admits that the Dexcom G6 was cleared through the De Novo classification process with general and special device-specific controls.

29. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 29 of the First Amended Complaint, and no response to the allegations in paragraph 29 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom further denies that plaintiff has accurately or completely characterized the premarket review process for Class III devices in paragraph 28 of the First Amended Complaint.

30. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 30 of the First Amended Complaint, and no response to the allegations in paragraph 30 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom further denies that plaintiff has accurately or completely characterized the premarket review process for Class III devices in paragraph 30 of the First Amended Complaint.

31. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 31 of the First Amended Complaint, and no response to the allegations in paragraph 31 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom further denies that plaintiff has accurately or completely characterized the premarket review process for Class III devices in paragraph 28 of the First Amended Complaint. Answering further, Dexcom responds that FDA undertakes scientific and regulatory review to evaluate safety and effectiveness of devices subject to the De Novo process.

32. The allegations in paragraph 32 are legal conclusions to which no response is required. To the extent a response is required, Dexcom admits only that 21 U.S.C. § 360e(d)(6)(A)(i) provides that "[a] supplemental application shall be required for any change to a device subject to an approved application under this

subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 360j(f) of this title."

33. The allegations in paragraph 33 are legal conclusions to which no response is required. To the extent a response is required, Dexcom admits that, after a PMA is approved to market a device, the manufacturer of the device is required to continue providing reports to the FDA and that the FDA has the power to revoke a PMA approval if it determines that a device is ineffective or unsafe under the conditions in its labeling. FDA likewise has the power to revoke any other marketing clearance if it determines that a device is ineffective or unsafe under the conditions in its labeling.

34. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 34 of the First Amended Complaint, and no response to the allegations in paragraph 34 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions.

35. The allegations in paragraph 35 are legal conclusions to which no response is required. To the extent a response is required, Dexcom admits that a manufacturer can receive permission to market a medical device through 510(k) review if the FDA concludes that the device a "substantially equivalent" to an already-approved predicate device. Answering further, "[a] 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is ***as safe and effective***, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act)." (emphasis added), available at: https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k. Premarket Notification 510(k); *see* also FDA Guidance, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications, issued December 27, 2011, at 6, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.

36. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 36 of the First Amended Complaint, and no response to the allegations in paragraph 36 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. The allegations in paragraph 36 are legal conclusions to which no response is required.

37. The allegations in paragraph 37 are legal conclusions to which no response is required.

38. The allegations in paragraph 38 are legal conclusions to which no response is required. Answering further, Dexcom states that both the Safe Medical Device Act Amendments of 1990 and FDA Memoranda (similar to the Guidance referenced in Dexcom's response to paragraph 35), confirm that safety and effectiveness are included in the 510(k) clearance process. *See* 21 U.S.C. 360(c)(1)-(3) (requiring *"reasonable assurance of safety and effectiveness"* of all devices irrespective of class and marketing pathway*)*; *see also* U.S. Food & Drug Admin, Mem., Public Health Interests and First Amendment Considerations Regarding Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, 40-44 (Jan. 17, 2017) (Docket No. FDA-2016-N-1149) (recognizing that "principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review," and that "approval application (PMA)... and 510(k)) differ in various ways, they all... enable[] FDA to ensure that devices on the market are ones that have been determined by FDA to have a reasonable assurance of safety and effectiveness."). Answering further, Dexcom responds that any applicable FDA regulatory framework contains federal requirements related to safety and effectiveness.

39. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 39 of the First Amended Complaint, and no response to the allegations in paragraph 39 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions.

40. The allegations in paragraph 40 are legal conclusions to which no response is required. To the extent a response is required, Dexcom admits that a manufacturer can request De Novo review of a Class II device.

41. The allegations in paragraph 41 are legal conclusions to which no response is required. To the extent a response is required, Dexcom denies plaintiff's allegations in paragraph 41 of the First Amended Complaint as stated to the extent that plaintiff suggests that devices cleared under the De Novo process are not subject to requirements regarding the safety and effectiveness of the device. Answering further, the De Novo process is an alternate pathway for novel Class II devices where general (such as labeling, device listing, registration requirements, quality systems, good manufacturing practices, post-market surveillance, data requirements, and performance standards) and special controls (device-specific requirements such as performance standard, post-market surveillance, patient registries, special labeling requirements, premarket data requirements, and guidelines) assure safety and

effectiveness for the intended use, but for which no predicate device has been legally marketed.

42. The allegations in paragraph 42 are legal conclusions to which no response is required.

ALLEGED FDA CLASSIFICATION AND REVIEW OF THE G6 SYSTEM

43. Dexcom admits the allegations in paragraph 43 of the First Amended Complaint.

44. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 44 of the First Amended Complaint, and no response to the allegations in paragraph 44 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom admits only that the Dexcom G6 was classified as a Class II device with the following special controls outlined in Exhibit 1 at 40-42, after being cleared by the FDA through the De Novo process, intended to provide reasonable assurances of the safety and effectiveness of the Dexcom G6 for intended users, adequate controls for secure and reliable inter-device communication, manufacturing controls for secure and reliable inter-device communication, to mitigate the risks identified above, and adequate transparency to allow the community to understand expected sensor performance:

(1) Design verification and validation, which includes "robust clinical data demonstrating the accuracy of the device in the intended use." Data must demonstrate that throughout the claimed sensor life, the device does not allow clinically significant gaps in sensor data availability that would prevent any digitally connected devices from achieving their intended use.

(2) Design verification and validation must include a detailed strategy to ensure secure and reliable means of iCGM data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the iCGM glucose data.

(3) Design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the performance specifications as defined in paragraphs (1) and (2) of this section.

(4) The device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances that are reasonably present in the intended use population, including but not limited to endogenous substances and metabolites, foods, dietary supplements, and medications.

(5) The device must include appropriate measures to ensure that disposable sensors cannot be used beyond its claimed sensor wear period.

(6) Design verification and validation must include results obtained through a usability study that demonstrates that the intended user can use the device safely and obtain the expected glucose measurement accuracy.

(7) The labeling must include a separate description of certain sensor performance data observed in the clinical study.

45. Dexcom admits that the Dexcom G6 was classified as a Class II device with special controls required by the FDA.

46. Dexcom admits that plaintiff attached the full and complete Reclassification Order as Exhibit B to her First Amended Complaint, but denies that she attached the full and complete Decision Summary indicating that the FDA classified the Dexcom G6 as a Class II medical device as Ex. C. *See* Ex. 1.

47. Dexcom admits FDA cleared the Dexcom G6 through the De Novo process for novel Class II medical devices, as alleged in paragraph 47 of the First Amended Complaint.

48. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 48 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the performance characteristics for the Dexcom G6. Dexcom therefore denies the allegations in paragraph 48 of the First Amended Complaint.

49. Plaintiff has not fully and completely quoted from the Decision Summary referenced in paragraph 49 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the performance characteristics for the Dexcom G6. Dexcom therefore denies the allegations in paragraph 49 of the First Amended Complaint.

50. Dexcom admits that it provided the User Guide for the Dexcom G6 to FDA in the De Novo application. Dexcom denies any other allegations in paragraph 50 of the First Amended Complaint.

51. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 51 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the data supporting reasonable assurance of safety and effectiveness for the Dexcom G6 and Dexcom's compliance with FDA's requirements. Dexcom further admits that FDA evaluated data from two G6 clinical studies "to support the accuracy performance of the device," as well as the design, manufacturing, and labeling of the G6 for safety and effectiveness.

52. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 51 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the data for the Dexcom G6. Dexcom admits that in order to grant Dexcom's De Novo application,

FDA evaluated data from two G6 clinical studies "to support the accuracy performance of the device," as well as the design, manufacturing, and labeling of the G6 for safety and effectiveness.

53. Dexcom admits that the Dexcom G6 was not required to undergo a PMA review prior to marketing, though all prior generations of the device did. Answering further, Dexcom states that the Dexcom G6 was submitted for 510(k) De Novo review by the FDA, and that FDA reviewed the safety and effectiveness of the Dexcom G6.

54. Dexcom admits that it was not required to submit a supplemental PMA to make changes to the Dexcom G6, and that it submitted 510(k) notifications to change the Dexcom G6, as FDA had previously determined that Dexcom provided reasonable assurances of safety and effectiveness of the device.

55. Dexcom denies the allegations in paragraph 55 of the First Amended Complaint.

56. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56 of the First Amended Complaint regarding Mr. Tuttle's alleged use of the Dexcom G6 System Mobile App, and therefore denies those allegations. Answering further, Dexcom states that modifications to software that do not impact the safety, effectiveness, or intended use of the device do not require submission of a new 510(k).

57. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide referenced in paragraph 57 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the compatibility of the Dexcom G6 with prior versions of Dexcom devices. Dexcom admits that certain components of the Dexcom G6 are not compatible with components from prior versions of Dexcom devices.

DEXCOM'S OTHER ALLEGED GLUCOSE MONITORING SYSTEMS

58. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 58 of the First Amended Complaint, and no response to the allegations in paragraph 58 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom admits that FDA reviewed and approved multiple generations of Dexcom's continuous glucose monitoring systems through the PMA process.

59. Dexcom admits that the Dexcom G4 Platinum CGMS was classified by FDA as a Class III medical device. Dexcom further admits that the Dexcom G6 was classified as a Class II device with special controls following De Novo review. In clearing the Dexcom G6 through the De Novo review process focused on the safety and effectiveness of the Dexcom G6, the FDA issued special controls applicable to

the Dexcom G6 and cleared the device for marketing. Dexcom denies all other allegations in paragraph 59 of the First Amended Complaint.

60. Dexcom admits that the Dexcom G4 Platinum CGMS was classified by FDA as a Class III medical device and that the Dexcom G6 was classified as a Class II device with special controls following De Novo review. Dexcom further admits that, although the Dexcom G6 was not approved through the PMA process, it was cleared following the FDA's review of a De Novo application that included assessment of the safety and effectiveness of the Dexcom G6, which resulted in requirements for the device. Dexcom denies all other allegations in paragraph 60 of the First Amended Complaint.

61. Dexcom admits that it routinely submits adverse event reports and that it has submitted annual reports for various devices in compliance with FDA regulations, but denies as stated the remaining allegations in paragraph 61 of the First Amended Complaint.

62. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 62 of the First Amended Complaint, and no response to the allegations in paragraph 62 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom further denies that the Dexcom G6 is not

subject to FDA review or that changes can be made to the Dexcom G6 that affect safety or effectiveness without submission of a new 510(k).

63. Dexcom denies that plaintiff has fairly or accurately characterized or summarized FDA's website as referenced in paragraph 63 of the First Amended Complaint, and no response to the allegations in paragraph 63 of the First Amended Complaint is required because the allegations are erroneous, incomplete, and are otherwise legal conclusions. Dexcom admits that it was required to submit PMA supplements for prior versions of the Dexcom G6. Dexcom further denies that the Dexcom G6 is not subject to FDA review or that changes can be made to the Dexcom G6 that affect safety or effectiveness without submission of a new 510(k).

MICHAEL TUTTLE'S ALLEGED USE OF THE G6 SYSTEM

64. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 64.

65. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 65 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 65.

66. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 66.

67. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 67.

68. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 68 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 68.

69. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 69.

70. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 70.

71. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 71.

72. Dexcom denies the allegations in paragraph 72 of the First Amended Complaint. Dexcom further denies that any product Dexcom designed, manufactured, sold, or distributed and that Mr. Tuttle obtained was defective in any way or otherwise caused his death.

73. Dexcom denies that plaintiff completely or accurately characterizes the document attached to the First Amended Complaint as Exhibit H, and further denies the allegations in paragraph 73 of the First Amended Complaint. Dexcom further denies that any product Dexcom designed, manufactured, sold, or distributed and that Mr. Tuttle obtained was defective in any way or otherwise caused his death.

74. Dexcom denies that plaintiff completely or accurately characterizes the document attached to the First Amended Complaint as Exhibit I, and further denies the allegations in paragraph 74 of the First Amended Complaint. Dexcom further denies that any product Dexcom designed, manufactured, sold, or distributed and that Mr. Tuttle obtained was defective in any way or otherwise caused his death.

75. Dexcom denies the allegations in paragraph 75 of the First Amended Complaint.

76. Dexcom lacks knowledge or information sufficient to form a belief as to whether Mr. Tuttle had a severe occurrence of hypoglycemia, as alleged in paragraph 76 of the First Amended Complaint. Dexcom denies the remaining allegations in paragraph 76 of the First Amended Complaint.

77. Dexcom lacks knowledge or information sufficient to form a belief as to whether Mr. Tuttle treated his hypoglycemia, as alleged in paragraph 77 of the First Amended Complaint. Dexcom denies the remaining allegations in paragraph 77 of the First Amended Complaint.

78. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 78.

79. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 79.

80. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 80.

81. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 81. Dexcom denies that any product Dexcom designed, manufactured, sold, or distributed and that Mr. Tuttle obtained was defective in any way or otherwise caused his death.

82. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 82.

83. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 of the First Amended Complaint. Therefore, Dexcom denies the allegations in paragraph 83.

84. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 of the First Amended Complaint as to whether Mr. Tuttle was using the Dexcom G6 System Mobile App version subject to recall on November 19, 2019, and therefore denies those allegations. Dexcom admits only that it initiated a voluntary recall of certain versions of the Dexcom G6 System Mobile App in November 2019, but denies that plaintiff completely or accurately characterizes the recall in paragraph 84 of the First Amended Complaint. Dexcom further denies that the Dexcom G6 System Mobile App was recalled on November 19, 2019, because it "was not properly alerting users." Dexcom denies all other allegations in paragraph 84 of the Amended Complaint.

85. Dexcom denies the allegations in paragraph 85 of the First Amended Complaint.

86. Dexcom denies the allegations in paragraph 86 of the First Amended Complaint.

COUNT ONE – ALLEGED STRICT LIABILITY

87. The allegations of paragraph 87 are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 87 of the First Amended Complaint.

88. The allegations of paragraph 88 are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 88 of the First Amended Complaint.

89. Dexcom admits only that one of the indications for use of the Dexcom G6 is to replace fingerstick blood glucose testing for diabetes treatment decisions.

90. Dexcom denies the allegations in paragraph 90 of the First Amended Complaint.

91. Dexcom denies the allegations in paragraph 91 of the First Amended Complaint.

92. Dexcom denies the allegations in paragraph 92 of the First Amended Complaint.

93. Dexcom denies the allegations in paragraph 93 of the First Amended Complaint.

94. Dexcom denies the allegations in paragraph 94 of the First Amended Complaint.

95. Dexcom denies the allegations in paragraph 95 of the First Amended Complaint.

96. Dexcom denies the allegations in paragraph 96 of the First Amended Complaint.

97. Dexcom denies the allegations in paragraph 97 of the First Amended Complaint.

COUNT TWO – ALLEGED NEGLIGENCE

98. Dexcom admits that it designs, manufactures, sells, and/or distributes the Dexcom G6. Dexcom admits that it provides a User Guide, attached to plaintiff's complaint as Exhibit A, that provides instructions and warnings related to use of the Dexcom G6 that were reviewed by and required by the FDA as part of its clearance of the Dexcom G6 through the 510(k) De Novo process.

99. The allegations of paragraph 99 are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 99 of the First Amended Complaint.

100. The allegations of paragraph 100 are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 100 of the First Amended Complaint.

101. Dexcom admits only that one of the indications for use of the Dexcom G6 is to replace fingerstick blood glucose testing for diabetes treatment decisions.

102. Dexcom denies the allegations in paragraph 102 of the First Amended Complaint.

103. Dexcom denies the allegations in paragraph 103 of the First Amended Complaint.

104. Dexcom denies the allegations in paragraph 104 of the First Amended Complaint.

105. Dexcom denies the allegations in paragraph 105 of the First Amended Complaint.

106. Dexcom denies the allegations in paragraph 106.

107. The allegations in paragraph 107 are legal conclusions and do not require a response. To the extent a response is required, Dexcom denies the allegations in paragraph 107 of the First Amended Complaint.

108. Dexcom denies the allegations in paragraph 108 of the First Amended Complaint.

COUNT THREE – ALLEGED BREACH OF WARRANTY

109. The allegations in paragraph 109 are legal conclusions and do not require a response. To the extent a response is required, Dexcom denies the allegations in paragraph 109 of the First Amended Complaint.

110. Dexcom lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110 of the First Amended Complaint, and therefore denies them.

111. Dexcom admits that it provided a User Guide for the Dexcom G6. Dexcom denies any other allegations in paragraph 111 of the First Amended Complaint.

112. The allegations in paragraph 112 of the First Amended Complaint are legal conclusions and no response is required. To the extent a response is required, Dexcom denies that the quoted language from the User Guide constitutes affirmation of fact or promises which were part of the basis of the sale of the Dexcom G6 to Mr. Tuttle. Dexcom admits that the User Guide provided numerous warnings to users about the risk of signal loss with the Dexcom G6 and notified users how to remedy a signal loss and how to take glucose measurements if a signal was lost.

113. The allegations in paragraph 113 of the First Amended Complaint are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 113 of the First Amended Complaint.

114. The allegations in paragraph 114 of the First Amended Complaint are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 114 of the First Amended Complaint.

115. Dexcom denies the allegations in paragraph 115 of the First Amended Complaint.

116. The allegations in paragraph 116 of the First Amended Complaint are legal conclusion and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 116 of the First Amended Complaint.

117. The allegations in paragraph 117 of the First Amended Complaint are legal conclusion and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 117 of the First Amended Complaint.

118. The allegations in paragraph 118 of the First Amended Complaint are legal conclusion and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 118 of the First Amended Complaint.

119. Plaintiff has not fully and completely quoted from the Dexcom G6 User Guide, Reclassification Order, and Decision Summary referenced in paragraph 119 of the First Amended Complaint, otherwise accurately characterized it, or provided a complete description of the indications for use of the Dexcom G6. Dexcom admits only that one of the indications for use of the Dexcom G6 is to replace fingerstick blood glucose testing for diabetes treatment decisions. Dexcom denies all other allegations in paragraph 119 of the First Amended Complaint.

120. Dexcom denies the allegations in paragraph 120 of the First Amended Complaint.

121. Dexcom denies the allegations in paragraph 121 of the First Amended Complaint.

122. Dexcom denies the allegations in paragraph 122 of the First Amended Complaint.

123. The allegations in paragraph 123 of the First Amended Complaint are legal conclusion and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 123 of the First Amended Complaint.

124. Dexcom denies the allegations in paragraph 124 of the First Amended Complaint.

COUNT FOUR – ALLEGED WRONGFUL DEATH

125. Dexcom lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 125 of the First Amended Complaint and therefore denies them.

126. The allegations in paragraph 126 of the First Amended Complaint are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 126 of the First Amended Complaint.

COUNT FIVE – ALLEGED PUNITIVE DAMAGES

127. The allegations in paragraph 127 of the First Amended Complaint are legal conclusions and no response is required. To the extent a response is required, Dexcom denies the allegations in paragraph 127 of the First Amended Complaint.

128. Dexcom denies the allegations in paragraph 128 of the First Amended Complaint.

129. Dexcom denies the allegations in paragraph 129 of the First Amended Complaint.

130. Dexcom denies the allegations in paragraph 130 of the First Amended Complaint.

131. Dexcom denies the allegations in paragraph 131 of the First Amended Complaint.

DEFENSES

1. The First Amended Complaint fails in whole or in part to state a claim upon which relief can be granted.

2. Plaintiff's claims are preempted by federal law, including, without limitation, 21 U.S.C. § 360k(a), and the United States Supreme Court's rulings in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

3. Plaintiff lacks standing to assert her claims.

4. Plaintiff has failed to plead her claims with sufficient particularity.

5. Any claim or cause of action that plaintiff may have had is barred by the applicable statutes of limitation and/or statutes of repose.

6. Plaintiff's claims are barred by the doctrine of unclean hands, laches, waiver and/or estoppel.

7. Plaintiff's claims are barred by the doctrine of primary jurisdiction.

8. Plaintiff's claims are barred by the doctrine of judicial estoppel.

9. The product that is the subject of the First Amended Complaint was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause plaintiffs' alleged damages.

10. Dexcom disclaimed and excluded "all other warranties, express or implied including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement" except for a limited warranty that the Dexcom G6 receiver would be "free from defects in material and workmanship under normal use . . . for the period starting from the date of shipment [to the user] and continuing for one year following the shipment date." Ex. 1 at 287.

11. The Dexcom G6 was not defective because, even if considered an inherently dangerous or unavoidably unsafe product under Georgia law, it was properly prepared, manufactured, packaged, and was accompanied with adequate warnings and instructions.

12. Plaintiff's alleged damages, if any, were caused, in whole or in part, by plaintiff's and/or decedent's own negligence and fault.

13. Plaintiff's alleged damages, if any, were caused solely by or contributed to by the act and fault of third parties for whom Dexcom is not liable or responsible.

14. There is no responsibility for either the acts or omissions of the knowledgeable users or misinformation or lack of information provided to plaintiff and/or decedent by others.

15. Plaintiff's damages, if any, were proximately caused by unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of Dexcom. The actions and omissions of Dexcom, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

16. Plaintiff and/or decedent were at fault, and such fault was either the sole or at least a proximate cause of their claimed injuries and/or damages. Such fault should bar or reduce proportionally plaintiff's recovery, if any, in accordance with Georgia law, and interpretative case law.

17. Any injuries or damages sustained by plaintiffs were directly and proximately caused by the failure of plaintiff and/or decedent to heed warnings and instructions.

18. If plaintiff sustained damages as alleged in the First Amended Complaint, which is denied, plaintiff and/or decedent failed to mitigate their damages.

19. Misuse of the product, which was not reasonably foreseeable, caused plaintiff's alleged damages, if any, and plaintiff's claims therefore may be barred or reduced by applicable law.

20. Plaintiff's claims are barred to the extent the injuries alleged in the First Amended Complaint were caused or enhanced by pre-existing or unrelated medical, genetic, environmental, or psychiatric conditions, diseases or illnesses, by plaintiff's and/or decedent's own idiosyncratic reactions, and/or by operation of nature.

21. Plaintiff's claims are barred on the grounds that plaintiff and/or decedent knew, or in the exercise ordinary care should have known, of the risks of the injuries or damages alleged in the First Amended Complaint, if any, and nevertheless, did freely and voluntarily assume said risks, and in this undertaking proximately caused and contributed to the losses, injuries, or damage, if any, alleged by plaintiff.

22. Plaintiff and/or decedent assumed all risks attendant with the use of the product that is the subject of the First Amended Complaint in a manner other than directed.

23. Plaintiff's claims are barred by the learned-intermediary and/or the sophisticated user doctrine.

24. Plaintiff's claims are barred, in whole or in part, from recovery due to spoliation of evidence.

25. Although Dexcom denies that plaintiff is entitled to judgment in any amount against it, Dexcom would show that any judgment against it is limited to the applicable amount or percentage of its liability under provisions of Georgia law, and Dexcom hereby invokes the provisions of same.

26. To the extent that the claims stated in the First Amended Complaint have been settled, compromised, or otherwise discharged, a set off is due.

27. Dexcom adopts and relies upon all provisions and defenses afforded it under Restatement (Second) of Torts, § 402A, including the comments thereto.

28. Dexcom reserves the right to raise all defenses provided in sections 2, 4, and 6 of the Restatement (Third) of Torts: Product Liability, if the Court finds that it is applicable in this case.

29. Dexcom incorporates all those defenses available under Georgia product liability law.

30. Dexcom adopts and relies upon all provisions and defenses afforded it under the United States Constitution and the Georgia Constitution.

31. The product that is the subject of the First Amended Complaint was not in an unreasonably dangerous condition.

32. Any fault on the part of Dexcom, which is denied, was not the proximate cause of and did not contribute to any or all of plaintiff's alleged damages.

33. The product that is the subject of the First Amended Complaint was not defective in manufacture, design, construction, or formulation and it conformed to all representations made by Dexcom.

34. If plaintiff suffered or sustained any injuries, loss, or damage as a result of the alleged incident referred to in the First Amended Complaint, the same were a direct result of Mr. Tuttle's failure to follow the reasonable advice of his healthcare providers and/or the warnings that accompanied the product.

35. The injuries or damages sustained by plaintiff, if any, may be attributed to several causes and accordingly should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

36. Any award of damages is subject to the limitations set forth under any applicable Georgia law.

37. If plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling or other unforeseeable misuse, or use inconsistent with the labeling of the Dexcom G6.

38. The First Amended Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the distribution of the Dexcom G6, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package

inserts and other literature, conformed to the applicable state of the art. The Dexcom G6, including its labeling reviewed by the FDA, complied with the state of scientific and medical knowledge available at the time.

39. The Dexcom G6 complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of the device, and that it was neither defective nor unreasonably dangerous.

40. The Dexcom G6 was not defective or unreasonably dangerous.

41. Dexcom relies on those defenses afforded to it by the Georgia Products Liability Act, codified at O.C.G.A. § 51-1-11, *et seq.*

42. The First Amended Complaint fails to state a claim with regard to any actions brought in products liability/strict liability to the extent that the Amended Complaint fails to state an amount sought to be recovered from any defendant, as required by O.C.G.A. § 51-1-11.

43. Plaintiff's claims are barred by additional defenses that may arise during the course of this litigation, which Dexcom reserves the right to assert.

WHEREFORE, having fully answered, defendant Dexcom, Inc., respectfully prays for the following relief:

1. That judgment is entered in its favor, dismissing the First Amended Complaint in its entirety with prejudice.

2. That judgment be entered in its favor for costs, expenses, and reasonable attorneys' fees incurred in connection with this matter; and

3. That this Court grant it such other and further relief, both at law and in equity, whether general or special, to which it may be justly entitled.

Dated: January 22, 2021

Respectfully submitted,

/s/ Zachary H. Fuller

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ATTORNEYS FOR DEXCOM, INC.

CERTIFICATION AS TO FONT

Counsel certifies that this pleading has been prepared in Times New Roman font in 14-point type.

/s/ Zachary H. Fuller

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of January, 2021, I have caused the foregoing to be filed and served upon all counsel of record via ECF.

/s/ Zachary H. Fuller
Zachary H. Fuller